ABSTRACT

A pharmaceutical dosage form such as a capsule capable of delivering therapeutic agents into the body in a time-controlled or position-controlled pulsatile release fashion, is composed of a multitude of multicoated particulates (beads, pellets, granules, etc.) made of one or more populations of beads. Each of these beads except an immediate release bead has at least two coated membrane barriers. One of the membrane barriers is composed of an enteric polymer while the second membrane barrier is composed of a mixture of water insoluble polymer and an enteric polymer. The composition and the thickness of the polymeric membrane barriers determine the lag time and duration of drug release from each of the bead populations. Optionally, an organic acid containing intermediate membrane may be applied for further modifying the lag time and/or the duration of drug release. The pulsatile delivery may comprise one or more pulses to provide a plasma concentration-time profile for a therapeutic agent, predicted based on both its pharmaco-kinetic and pharmaco-dynamic considerations and in vitro/in vivo correlations.